

JUN 29 2012

**510(k) Summary
for the WAVE O Cage**

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the WAVE O Cage

1. GENERAL INFORMATION

Date Prepared: April 17, 2012

Trade Name: WAVE O Cage

Common Name: intervertebral body fusion device

Classification

Name: Intervertebral body fusion device - lumbar

Class: II

Product Code: MAX

CFR section: 21 CFR section 888.3080

Device panel: Orthopedic

Legally Marketed

Predicate Device: Distractable WAVE Cage - K083626

Submitter: Advanced Medical Technologies AG
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Germany

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2. DEVICE DESCRIPTION

The WAVE O cage is an expandable PEEK cage of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

Materials:

PEEK-OPTIMA LT1 polymer (ASTM F2026 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications).

Tantalum (ISO 13782 / ASTM F560)

Function:

The WAVE-O Cage was developed as an implant for the posterior stabilization of the lumbar spinal column.

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The WAVE-O Cage is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

The WAVE O Cage is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive unilateral posterior approach. Alternatively, these implants may also be implanted via a transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

5. NON-CLINICAL TEST SUMMARY

Dynamic compression per ASTM F1717
Finite element analysis

The results of this testing indicate that the WAVE O Cage is equivalent to predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

This summary includes the conclusions drawn from the nonclinical tests (discussed above) that demonstrate that WAVE O Cage is as safe and performs as well as the predicate device(s).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced Medical Technologies AG
% Mr. J.D. Webb
1001 Oakwood Blvd
Round Rock, Texas 78681

JUN 29 2012

Re: K121330
Trade/Device Name: WAVE O Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 27, 2012
Received: May 3, 2012

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

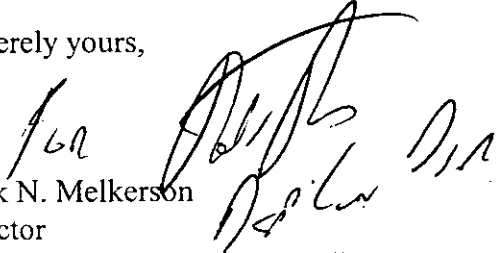
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: WAVE O Cage

Indications for Use:

The WAVE O Cage is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive unilateral posterior approach. Alternatively, these implants may also be implanted via a transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical Orthopedic,
and Restorative Devices

510(k) Number K121330